

STUDY DEVICE: KeraStat Cream

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VERSION: 01

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**ICF: KERASTAT® CREAM FOR RADIATION
DERMATITIS**

Sponsor: KeraNetics, LLC
200 East 1st Street, Suite 101
Winston-Salem, North Carolina 27101
USA
Tel: 336 725 0621
Fax: 336 725 0619

WAKE FOREST School of Medicine

Informed Consent Template

Instructions:

- *This template is designed to provide assistance and guidance in the construction of research informed consent documents. While it addresses many issues, it does not address every possible situation or issue that may arise. Investigators should use this document for what it is, a template. Investigators must include all study specific information that a potential research subject should be aware of in order to make an informed, voluntary decision about taking part in the study.*
- *Model text is in **bold** and should be converted to normal text (not bold)*
- *Instructions in [italics] should be deleted.*
- *A blank (_____) indicates to fill in the required information as appropriate and remove the underlining. Delete the sections that are not appropriate.*
- *The descriptions and information should be in lay language, defined as language understandable to the people being asked to participate (usually 6th to 7th grade). The final version should be checked for reading level.*
- *The use of second person (e.g., "You will receive...") is generally required; the use the first person (e.g., "I understand that...") is generally not allowed.*
- *Individual involved in the study should be referred to as subjects or participants not patients.*
- *The informed consent should state facts rather than require attestations on the part of the subject.*
- *The final version should be spell checked and carefully proof-read to insure correct spelling, sentence construction, information flow, readability and formatting.*
- *When submitting the informed consent form using this template as a guide, pages 1 and 2 of this document should be deleted.*

PILOT STUDY OF KERASTAT® CREAM FOR RADIATION DERMATITIS
DURING HEAD AND NECK RADIOTHERAPY

Informed Consent Form to Participate in Research
Karen M. Winkfield, MD PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to test the feasibility of a new cream for skin care during radiation treatments head and neck cancer. You are invited to be in this study because you have head and neck cancer and are planned to undergo radiation treatment. Your participation in this research will involve 8-9 visits over the course of your radiation treatments and last about the length of your radiation treatment plus one month.

Participation in this study will involve using a cream on your neck to prevent radiation skin irritation. This will either be the study agent or regular skin cream (readily available over the counter) as directed by your doctor. All research studies involve some risks. A risk to this study that you should be aware of is discomfort related to the cream. There is a possibility that you may benefit from participation in this study, if the study cream is better at preventing radiation skin irritation than regular creams. This study is not meant to compare which cream is better at preventing this skin irritation.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include using routine skin care as would otherwise be directed by your doctor. This would be the same skin care that you would use even if you did not participate in the study. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Dr. Karen Winkfield. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his/her contact information is: Dr. Karen Winkfield, Department of Radiation Oncology, Medical Center Blvd, Winston Salem, NC 27157; telephone: 336-713-3600, fax 336-713-6622.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at 336-716-4542 or the Research Subject Advocate at Wake Forest at 336-716-8372.

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you have head and neck cancer and are planned to undergo radiation treatments. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to test if it is feasible to use a new cream to prevent radiation skin irritation in patients undergoing head and neck radiation treatments. This will provide information that will be used to create other studies with this cream in the future. The study cream, KeraStat Cream, is an investigational topical agent/device. This means it has not been approved by the U.S. Food and Drug Administration (FDA). Drugs and devices that do not have approval by the FDA cannot be sold or prescribed by your physician. In this study KeraStat Cream will be compared to routine skin care, which is any regularly-available cream that your doctor would recommend for you to use during radiation treatments regardless of whether you are on this study or not.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

24 people at Wake Forest Baptist Comprehensive Cancer Center will take part in this study, including approximately number people at this research site. In order to identify the 24 subjects needed, we may need to screen as many as 26 because some people will not qualify to be included in the study.

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in any group.

You will be treated for your head and neck cancer the same as you would be treated if you were not on this study. Prior to starting your radiation treatments, your demographics, medical history, medication use will be collected. You will be asked to complete 2 short questionnaires regarding your skin and how it feels (skin-related quality of life). Study staff will then take photos of your skin in the head and neck area to be treated. These will be kept safe and confidential.

You will then be randomized to the study cream or routine skin care. If you are randomized to the study cream group, we will provide you with the study cream. If you are randomized to the routine skin care group, your doctor will provide you with a list of recommended over-the-counter creams. Routine skin care is what would be recommended if you were not participating in this study. You will be provided with instructions on how to use the cream you are assigned to.

When you begin radiation treatment, you will generally see your doctor once a week for routine on-treatment visits. These would occur whether or not you participate in this study. At these weekly visits, you will be asked to complete the skin quality of life questionnaires. You will also be asked how often you were able to apply the cream and whether you had to stop using the cream for any reason. If you were randomized to the study cream group, you will be asked how much cream it took to cover your entire neck with cream over the preceding week. Study staff will also take pictures of the skin in that area to keep track of the radiation skin irritation as you go through treatment.

After completing treatment, you will generally return to see your doctor for a follow-up visit about 1 month later. This visit would occur whether or not you choose to participate in this study. At this visit, you will be asked the same questions and asked to complete the same skin quality of life questionnaires as when you were on-treatment. After this visit, the study will end.

In total, this study will take approximately 8-9 visits: 1 visit prior to treatment, 6-7 weekly visits during treatment, and 1 visit after treatment. All of these will occur at the same time as your routine treatment visits and routine follow-up visit. There are no extra visits required to participate in this study.

If you take part in this study, you will undergo radiation treatment as part of standard of care. This is the same treatment whether or not you choose to participate in the study. You will also be seen once weekly during radiation treatment and be seen 1 month after completing radiation. These visits will also occur whether or not you choose to participate in this study. During treatment, you will be instructed to use skin cream at least twice daily.

As part of this research study, the part of your skin in the head and neck area will be photographed. This is being done to keep track of the skin irritation that occurs as a normal part of radiation treatment for head and neck cancer. You understand that you may request the photography be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photographs before they are used. You should also understand that you will not be able to inspect, review, or approve the photographs before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the photographs/videotapes/audiotapes of me to be destroyed once their use in this study is finished.

_____ The photographs/videotapes/audiotapes of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 12 weeks. This includes the pre-radiation visit, weekly visits during radiation (6-7 weeks, prescribed by your doctor regardless of participation in this study), and one visit approximately 4 weeks after you finish radiation. You can stop participating at any time. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences.

WHAT ARE THE RISKS OF THE STUDY?

Being treated with radiation treatments always involves some risk to you. You should discuss the risk of being in this study with your doctor. Being involved in this study involves some risk to you. These risks are generally minimal, and may include discomfort related to the use of the study cream.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have this option: routine skin care as directed by your doctor. Routine skin care is one of the groups in this study, and is generally the accepted standard of care. If you do not take part in this study, you will not be eligible to receive the study cream (KeraStat cream).

WHAT ARE THE COSTS?

All study costs, including any study medications and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. If you are randomized to the study cream group, you will be supplied with the cream free of charge. Neither you nor your insurance company will be billed

for the investigational device.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

The purpose of this research study is to obtain data or information on the feasibility of use of KeraStat cream; the results will be provided to the sponsor, the Food and Drug Administration and other federal and regulatory agencies as required.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences through a partnership with KeraNetics. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

What About My Health Information?

In this research study, any new information we collect from you or your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: demographic information, medical history, medications, skin irritation and quality of life metrics, and photographs of just the skin in the area treated with head and neck radiation.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store

records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you (“your health information”) may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

You can tell Dr. Winkfield that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Dr. Karen M. Winkfield, MD PhD
Department of Radiation Oncology
Medical Center Blvd
Winston Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people

who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because it is in your best interest, your condition has worsened, new information becomes available, you failed to follow instructions, or the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Name at telephone number (also include after hours number).

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at (336) 716-4542 or the Research Subject Advocate at (336) 716-8372.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed): _____

Subject Signature: _____ Date: _____ Time: _____ am pm

Person Obtaining Consent (Printed): _____

Person Obtaining Consent: _____ Date: _____ Time: _____ am pm